Evaluation of the kinetics of a whole blood assay (quantiferon- TB Gold) measuring M. Tuberculosis-specific immune responses in military personnel with a positive tuberculin skin test

Published: 19-12-2006
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Objectives* The primary aim is to study the kinetics of QFT-G in military personnel with a positive TST result. * Secondary aims are to study the practical feasibility of using QFT-G in the setting of a military hospital.Next to this we wish to...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mycobacterial infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON29868

Source
ToetsingOnline

Brief title
Kinetics of Quantiferon test in latent Tuberculosis Infection

Condition

- Mycobacterial infectious disorders
- Respiratory tract infections

Synonym
latent tuberculosis, tuberculosis infection

Research involving
Human

Sponsors and support

Primary sponsor: Centraal Militair Hospitaal
Source(s) of monetary or material Support: Ministerie van Defensie

Intervention

Keyword: Army, Kinetics, Latent TB, Quantiferon TB test (QFT-G)

Outcome measures

Primary outcome

sequential results of QFT-G test

Secondary outcome

0

Study description

Background summary

Short title
Evaluation of the kinetics of the Quantiferon TB Gold whole blood assay measuring M. tuberculosis-specific immune responses in military personnel with a positive tuberculin skin test.

Background
The detection and treatment of latent tuberculosis (TB) infection in military personnel has thus far been based on the tuberculin skin test (TST). Once the TST has been found to be positive, it remains positive and can no longer be used for the detection of reinfection. In a previous study, Quantiferon TB Gold (QFT-G), a whole blood assay specific for MTB infection was evaluated in 900 subjects. Results showed that positive QFT-G results were found in only a minority of individuals with a positive TST. This could be due either to false-positive TST results due to exposure to environmental mycobacteria or due to conversion from QFT-G positive to negative, either spontaneously or during treatment.

Study objective

Objectives
* The primary aim is to study the kinetics of QFT-G in military personnel with

a positive TST result.
* Secondary aims are to study the practical feasibility of using QFT-G in the setting of a military hospital.
Next to this we wish to confirm/ investigate the reproducibility of the result of previous study. IF so ,then there will be an urgent need to revisit the current approach /guidelines of treatment of latent tuberculosis.

Study design

Design
All military personnel who are treated for a recently detected positive TST result will undergo serial QFT-G at 0, 2, 6 and 12 months. Those who decline treatment for latent TB infection will be followed at 0, 6, 12, 18 and 24 months. This is an observational study, indicating that the results of the novel comparative assay will not be used for clinical decision making. The results of the QFT-G will be blinded until the end of the study. Standard care will be provided according to existing protocol, e.g. chest radiography will be performed in all persons with a positive TST.

Intervention
A blood sample (2 ml) will be collected at each time point during follow-up. The study does not interfere with standard medical care.

Follow-up
Subjects with a positive TST who are treated will be seen at 0, 2, 6 and 12 months. Those who decline treatment will be followed at 0, 6, 12, 18 and 24 months.

Analysis
Descriptive summary statistics, time course of QFT-G results in relation to treatment.

Study burden and risks

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Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

military personnel of Dutch army
recent positive Mantoux

Exclusion criteria

known immune defect (HIV), BCG vaccin, previous positive Mantoux

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-02-2007
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO

Date:	19-12-2006
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL13753.041.06